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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,449

03/30/2004

Enrique J. Klein

6766USC5

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57360 7590 01/25/2008  
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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

01/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/813,449		KLEIN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Katherine Dowe		3734	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5-14,16-20,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-14,16-20,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/03/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 3-4, 15, 21 and 22 have been cancelled by Applicant as they were directed to a non-elected invention. Election was made **without** traverse in the reply filed on 3/02/2007.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) received on 3/03/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 recites the limitation "suture ports" in line 3. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 5-14, 16-20, and 23-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Hathaway, U.S. 5,304,184.

Hathaway discloses a suturing apparatus and related methods.

Hathaway's method comprises, "grabbing the sutures with the retrieval assembly on the distal side of the tissue membrane; retrieving the sutures through the opening by withdrawing the retrieval assembly out through the opening; and, drawing together the suture location with the sutures." Hathaway, col. 2, lines 50-54.

"The apparatus further includes an array of at least two needles disposed around the tubular body which carry a respective length of suture. The array of needles is advanceable through the tissue to a distal side thereof to provide sutures at separate suture locations in the tissue membrane around the opening." Id. at col. 2, lines 62-68.

"The needles are advanced through the tissue membrane at various suture locations caused by the puncturing action of the needles. The needles carry suture or other suitable surgical closure materials." Id. at col. 5, lines 62-65.

"Fig. 12 illustrates retrieval assembly 51 completely withdrawn from apparatus 50. Such withdrawal is accomplished by pulling the retrieval assembly, including elongated tube member 63 and distal end 53, out of the lumen of sheath 56. Since the sutures, such as suture 58, are still connected to distal end 53, the withdrawal pulls the

sutures out of magazine 60 distally through the suture locations in the tissue membrane. The sutures are thereby doubled back and pulled outwardly through the lumen of sheath 56.

"Apparatus 50 is thereafter withdrawn from opening 99 and opening 41 in the patient, carrying the sutures outwardly through opening 41." Id. at col. 6, lines 36-48.

"Thereafter, apparatus 50 is removed entirely with the sutures being separated (by cutting or otherwise) so that what remains are four lengths of suture (each doubled back) threaded through a respective four suture locations around opening 99 in the blood vessel." Id. at col. 6, lines 54-59.

From the foregoing disclosure it can be seen that Hathaway discloses what is substantially claimed by Applicant. Specifically, Hathaway discloses a method for suturing tissue in proximity of an aperture in a tissue wall, comprising: forming a port within the tissue wall in proximity of said aperture (Fig. 9); passing at least a portion of suture from the distal side of the tissue wall proximally through the port in the tissue wall (Fig. 12); and forming a loop with the remaining portion of the suture to secure the suture (Fig. 14a). The suture is pulled from the distal side of the tissue wall as it is drawn back through the tissue wall as shown in figures 11-13. Engaging the suture with the needle can be said to be performed throughout the procedure. The needles engage suture ports on opposite sides of the aperture. The suture portion is removed from the needles after removing the needles from the vessel and the portions of the suture are secured over the wall of the vessel to close an aperture. See Fig. 14.

The pair of needles can be said to move in a path which is radially angled to the elongated member as the needles pass through the vessel wall; i.e. an angle of 180 or 0 degrees. Further, the ends of the needles move radially outwardly from the elongated member prior to passing through the vessel wall. Cf. figures 7 & 8.

The holes are disposed transversely across the width of the vessel wall. See Fig. 13.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Amarasinghe, U.S. 4,553,543.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

kmd

A handwritten signature in black ink, appearing to read "MJ Hayes", is positioned above the printed name.

MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER